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I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

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PATENT TRADEMARK OFFICE

Docket No.: 2427/1-5509

TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Alessandra D'AZZO; Antonella BONGIOVANNI; Tommaso NASTASI

Serial No.: 10/014,774

Confirmation No.: 9922

Filed: October 29, 2001

For: PROTEIN SPECIFIC FOR CARDIAC AND SKELETAL MUSCLE

May 7, 2002

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

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Sir:

GROUP 3600

This Supplemental Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related

application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- ☐ A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment

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hereto. A copy of each document listed is attached, except as explained below.

(check boxes A and/or B and fill in blanks, if appropriate.)

- ☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ B. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

[SERIAL NO. & FILING DATE].

Applicant Identifies these documents by attaching hereto copies of the forms PTO- 892 and PTO- 1449 from the files of the prior application(s) or a fresh PTO- 1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document(s) _____ are not in the English language. In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- ☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see MPEP § 609 A(3)x).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.

☐ 4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

☐ 5. Other information being provided for the examiner's consideration follows:

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

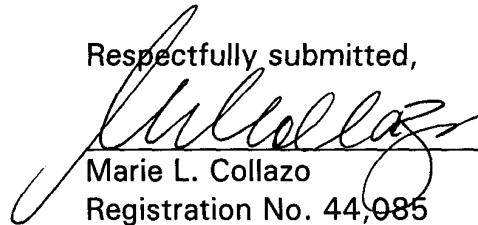
CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Provisional Patent Application Serial No. 60/131,814, filed April 29, 1999.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,



Marie L. Collazo
Registration No. 44,085

DARBY & DARBY P.C.
805 Third Avenue
New York, N.Y. 10022
(212) 527-7700

Docket No. 2427/1F509-US1

**LIST OF REFERENCES CITED BY APPLICANT**

(Use Several Sheets if Necessary)

DOCKET NO.: 2427/1F509 SERIAL NO: 10/014,774
 APPLICANT: Alessandra D'AZZO FILING DATE: October 29, 2001
 CONFIRMATION NO: 9922

U.S. PATENT DOCUMENTS

<u>*EXAMINER</u> <u>INITIALS</u>	<u>DOCUMENT</u> <u>NUMBER</u>	<u>DATE</u>	<u>NAME</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>FILING DATE</u>
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FOREIGN PATENT DOCUMENTS

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<u>*EXAMINER</u> <u>INITIALS</u>	<u>DOCUMENT</u> <u>NUMBER</u>	<u>DATE</u>	<u>COUNTRY</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>YES</u>	<u>NO</u>
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OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

*EXAMINER
INITIALS

1. Giljart, N.J., et al., "Expression of cDNA Encoding the Human "Protective Protein" Associated with Lysosomal B-Galactosidase and Neuraminidase; homology to Yeast Proteases" Cell 54:755-764 (1988).
2. Giljart, N.J., et al., "Mouse "Protective Protein" cDNA Cloning, Sequence Comparison and Expression" J. Biol. Chem. 265:4678-4684 (1990).
3. Wiegant, J., et al., "The Gene Encoding Human Protective Protein (PPGB) Is on Chromosome 20" Genomics, 10:345-349 (1991).
4. Williamson, C.M., et al., "Protective Protein for B-galactosidase, Ppqb, Maps to the Distal Imprinting Region of Mouse Chromosome 2 but Is Not Imprinted", Genomics, 22:240-242 (1994).
5. Shimomoto, M., et al., "A Human Protective Protein Gene Partially Overlaps the Gene Encoding Phospholipid Transfer Protein on the Complementary Strand of DNA" Biochem Biophys Res Comm 220:802-806 (1996).

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FORM PTO-1449

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SHEET 2 OF 2
(REV. 7-80)

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LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 2427/1F509
APPLICANT: Alessandra D'AZZO

SERIAL NO: 10/014,774
FILING DATE: October 29, 2001
CONFIRMATION NO: 9922

*EXAMINER
INITIALS

6. Bridgeman, A., EMBL/GenBank/DBJ databases (Submitted April 27, 1998). Chromosome 20 Project Group (<http://www.sanger.ac.uk/HGP/Chr20/>) Sanger Centre.

7. Lee N.H., et al., "Rat Genome Project: Generation of a Rat EST (REST) Catalog & Rat Gene Index" Unpublished, (created - Feb. 11, 1998), The Institute for Genomic Research.

8. NCI-CGAP, "National Cancer Institute, Cancer Genome Anatomy Project (CGAP), Tumor Gene Index <http://www.ncbi.nlm.nih.gov/ncicgap>" (created - April 26, 1999), Unpublished.

EXAMINER: _____

DATE CONSIDERED: _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.